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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 2004D–0361]**

# Guidance for Industry: Prior Notice of Imported Food Contingency Plan for System Outages; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and Customs and Border Protection (CBP) program systems. Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and its implementing regulations require prior notice to FDA of all food imported or offered for import into the United States.

**DATES:** This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://*



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*www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703–621–7809.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58974), FDA issued an interim final rule (IFR) to implement section 307 of the Bioterrorism Act. The prior notice IFR requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The prior notice IFR provides that if a customs broker's or self-filer's system is not working or if the Automated Broker Interface of the Automated Commercial System is not working, prior notice must be submitted through the Prior Notice System Interface (PNSI); and that if PNSI or the Operational and Administrative System for Import Support is not operating, prior notice information must be submitted by e-mail or by fax to FDA.

We stated in the prior notice IFR that FDA does not plan to exempt any specific categories of food articles from prior notice if system(s) are not working, and that FDA and CBP are working together to develop contingency plans for when the applicable FDA and CBP program systems are not working (68 FR 58974 at 58997). FDA with concurrence from CBP is announcing the availability of a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and CBP program systems. The contingency plan identifies seven potential system downtime scenarios that could impact transmission, confirmation, and

processing of prior notice submissions and explains recommended submission options for each of the identified scenarios. In any of the scenarios described in the contingency plan, where the alternate submission options include both e-mail and fax (telephonic facsimile) transmissions, e-mail transmission is strongly encouraged as the more efficient means.

FDA is issuing this document as a level 1 guidance consistent with FDA's good guidance practices regulation (§10.115 (21 CFR 10.115)). The contingency plan is being implemented immediately without prior public comment, under §10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. Under section 307 of the Bioterrorism Act, the prior notice requirements were effective December 12, 2003, and FDA and CBP's systems for processing prior notice submissions are up and running, making it urgent that the agencies explain how submitters can fulfill the prior notice requirements in the event of system outages.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/oc/bioterrorism/bioact.html.*

Dated: 8/11/04

August 11, 2004.

John Marzilli,
Acting Associate Commissioner for Regulatory Affairs.

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